

## **REMARKS**

Claims 9, 14, 57, and 61, as amended, and claims 13, 16, 46, 47, 59, and 60 are pending in the instant application. No new matter has been added as a result of the above-described amendments. The rejections set forth in the Office Action have been overcome by amendment or are traversed by argument below.

### **1. Rejection of claims 9 and 59 under 35 U.S.C. § 101**

The Office Action asserts a rejection of claims 9 and 59 under 35 U.S.C. § 101 as being directed to non-statutory subject matter. The Action states that because the polypeptide recited in claims 9 and 59 is not necessarily isolated, and claims 9 and 59 encompass a polypeptide that occurs naturally in cultured eukaryotic cells (*i.e.*, the polypeptide of SEQ ID NO: 5), the process recited in claims 9 and 59 will produce a polypeptide identical to or indistinguishable from the naturally occurring polypeptide. The Examiner suggests that this rejection can be overcome by amending claim 9 to recite an "isolated polypeptide."

Applicants have amended claim 9 as suggested by the Examiner to recite an "isolated polypeptide." Applicants, therefore, respectfully request that this ground of rejection be withdrawn.

### **2. Rejection of claims 14, 46, 47, and 61 under 35 U.S.C. § 112, first paragraph**

The Office Action asserts a rejection of claims 14, 46, 47, and 61 under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Action states that the specification does not provide an adequate written description of the polypeptide fragments recited in claims 14 and 61 because the description of the polypeptide of SEQ ID NO: 5 is not representative of at least a substantial number of the polypeptide fragments encompassed by these claims. The Action states that the description of the polypeptide of SEQ ID NO: 5 is not representative of the claimed genus of polypeptide fragments because the polypeptide fragments are not described as sharing a particularly identifying and substantial structural feature of the polypeptide of SEQ ID NO: 5 which correlates with a functional attribute of the polypeptide of SEQ ID NO: 5. The Action therefore concludes that

the skilled artisan could not immediately envision, recognize, or distinguish at least a substantial number of the claimed polypeptide fragments.

Applicants respectfully disagree with the Action's assertion that the invention as presently claimed has not been adequately described. Applicants understand the Action's assertion that the description of the polypeptide of SEQ ID NO: 5 is not representative of the claimed genus of polypeptide fragments to be *primarily* based on the limitation in claims 14 and 61 that the recited polypeptide fragments "upon injection into an animal produces an antibody that binds to the polypeptide set forth in SEQ ID NO: 5." Applicants note, however, that it was the Examiner who suggested the above functional limitation in a Proposed Examiner's Amendment mailed May 9, 2002 in corresponding U.S. Application No. 09/599,087. Notwithstanding the origins of this now objected-to limitation, because Applicants believe that claims 14 and 61 satisfy the written description requirement without this limitation, Applicants have amended claims 14, 57, and 61 to delete it.

Applicants contend that because the specification *explicitly* teaches (a) the amino acid sequence for human Secs-1 polypeptide (Figure 2), (b) that the term "Secs-1 polypeptide fragment" refers to a polypeptide that comprises a truncation at the amino-terminus and/or a truncation at the carboxyl-terminus of the polypeptide of SEQ ID NO: 5 (*see, e.g.*, page 11, lines 12-15), (c) that Secs-1 polypeptide fragments comprise at least 25 amino acids (*see, e.g.*, page 11, lines 25-26), and (d) that the full-length Secs-1 polypeptide is 81 amino acids in length (Figure 2), the specification *inherently* discloses polypeptide fragments of at least about 25 amino acid residues, but not more than 80 amino acid residues, of human Secs-1 polypeptide, since polypeptide fragments are merely portions of the specifically disclosed full-length human Secs-1 polypeptide sequence. In other words, in view of the above teachings, one of ordinary skill in the art would be able to readily envision *every member* of the claimed genus of polypeptide fragments.

Furthermore, Applicants contend that there is no support for the assertion that the description of an amino acid sequence (such as that provided in the SEQ ID NO: 5 of the instant specification) is insufficient to support a claim to polypeptide fragments of that sequence. Applicants contend that in view of the explicitly-disclosed sequence provided by the instant application, one of ordinary skill in the art could *readily* determine the structure of polypeptide fragments of SEQ ID NO: 5, and would

recognize that Applicants were in possession of the claimed invention. Applicants, therefore, submit that claims 14 and 61, as amended, satisfy the written description requirement of 35 U.S.C. § 112, first paragraph.

**3. Rejections of claims 9 and 59 under 35 U.S.C. § 102(b)**

The Office Action asserts a rejection of claims 9 and 59 under 35 U.S.C. § 102(b), as being anticipated by Marchis-Mouren *et al.*, 1988, *Biochimie*. 70:663-71. The Action states that absent a showing otherwise, the human colon cancer cell line (HT-29) disclosed by Marchas-Mouren *et al.* is deemed to produce a polypeptide that is indistinguishable from the polypeptide of SEQ ID NO: 5. The Action therefore concludes that because the polypeptide recited in claims 9 and 59 is not necessarily isolated, claims 9 and 59 encompass a polypeptide that is indistinguishable from the polypeptide produced by the HT-29 cells disclosed by Marchis-Mouren *et al.*

As described in section 1 above, Applicants have amended claim 9 to recite an "isolated polypeptide." Applicants contend that because claims 9 and 59, as amended, are directed to an isolated polypeptide, these claims do not encompass a polypeptide that is indistinguishable from the polypeptide presumed by the Examiner to be produced by the HT-29 cells disclosed by Marchis-Mouren *et al.* Applicants, therefore, respectfully request that this ground of rejection be withdrawn.

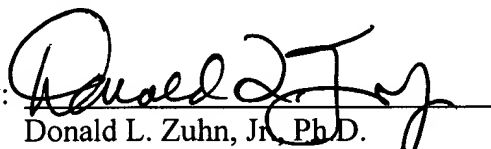
**CONCLUSION**

Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended. Allowance of the claims is thereby respectfully solicited.

If Examiner Rawlings believes it to be helpful, he is invited to contact the undersigned representative by telephone at 312-913-0001.

Respectfully submitted,  
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